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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/633,743	08/04/2003	Sean Rees Klopfenstein	9018M2	5602

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EXAMINER

ANDERSON, REBECCA L

ART UNIT PAPER NUMBER

1626

DATE MAILED: 12/28/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/633,743	Applicant(s) KLOPFENSTEIN ET AL.	
	Examiner Rebecca L. Anderson	Art Unit 1626	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 22 September 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-21 is/are pending in the application.
- 4a) Of the above claim(s) 6-15, 17, 19 and 20 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-5, 16 and 21 is/are rejected.
- 7) ☒ Claim(s) 1-5, 16, 18 and 21 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|-------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>1/04</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claims 1-21 are currently pending in the instant application. Claims 6-15, 17, 19 and 20 are objected, claims 1-5, 16, 18 and 21 are objected and claims 1-5, 16 and 21 are rejected.

Election/Restrictions

Applicant's election with traverse of Group I, claims 1-18 and 21 and the further election the compound of example 63 in the reply filed on 22 September 2005 is acknowledged. The traversal is on the ground(s) that according to MPEP 803, the inventions are closely interrelated and in order to preserve unity of invention, all the claims should be prosecuted in the same application and there is no undue burden of search on the Examiner. This is not found persuasive because it is noted that the restriction requirement was made under 35 USC 121. 35 USC 121 gives the Commissioner (Director) the authority to limit the examination of an application where two or more independent and distinct inventions are claimed to only one invention. The examiner has indicated that more than one independent and distinct invention is claimed in this application and has restricted (limited) claimed subject matter accordingly. Thus the requirement to restrict the claims in this application is predicated on the fact that the claimed subject matter involves more than one independent and distinct invention. Nowhere do applicants argue to the contrary. No where do applicants point out and give reasons why the claims do not involve independent or distinct subject matter. Rather, applicant has argued a lack of unity standard, which does not address the premise of the restriction requirement. Notwithstanding that lack of unity is not the

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basis for this restriction requirement, a lack of unity standard requires that the claims contain a special technical feature that defines a contribution over the art. Here the claims contain a product of the formula (I) which does not define a contribution over the art as can be seen by the following 35 USC 102(b) rejection of the non-elected subject matter of claims 1-5, 16 and 21. So, here we have claims, which involve more than one independent or distinct inventions. Under 35 USC 121, the claims may be restricted and the examination limited to a restricted invention. Thus, the requirement to restrict in this application is predicated on the fact that the elected subject matter taken as a whole and the non-elected subject matter taken as a whole are so different in structure and element as to be patentably distinct, i.e. a reference which anticipated but one group of compounds would not even render obvious the other group. In response to the lack of burdensome search argument, it is noted that the inventions are independent and distinct because there is no patentable co-action between the groups and a reference anticipating one member will not render another obvious. Each group is directed to art recognized divergent subject matter, which require different searching strategies for each group. Moreover, the examiner must perform a commercial database search on the subject matter of each group in addition to a paper search, which is quite burdensome to the examiner.

Therefore, as stated on pages 3 and 4 of the restriction requirement, **the elected invention for search and examination is:**

The products of formula I wherein:

A) **R1** is $-L1-[C(R6aR6b)]mR7$, wherein:

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- a) **L1** is --CO-- ;
 - b) one of **R6a** and **R6b** is hydrogen and the other is $\text{--NHCO}_2\text{R}_9$;
 - c) **m** is 1;
 - d) **R7** is substituted or unsubstituted aryl or alkylenearyl;
 - e) **R9** is substituted or unsubstituted C1-C5 alkyl;
- B) **R2** is $\text{--(CH}_2\text{)}_j\text{--L}_2\text{--[C(R}_{11}\text{aR}_{11}\text{b)}]_g\text{R}_{12}$, wherein:
- a) **j** is 0;
 - b) **L2** is $\text{--CON(R}_{10}\text{)--}$;
 - c) **R10** is hydrogen or substituted or unsubstituted C1-C5 alkyl;
 - d) **g** is 0;
 - e) **R12** is hydrogen or substituted or unsubstituted C1-C10 alkyl;
- C) **R3** is $\text{--(CH}_2\text{)}_n\text{--L}_3\text{--R}_{16}$, wherein:
- a) **n** is 0;
 - b) **L3** is a covalent bond;
 - c) **R16** is hydrogen; and
- D) **R4a**, **R4b**, **R4c** and **R5** are hydrogen.

The remaining subject matter of claims 1-5, 16, 18 and 21 not drawn to the above elected invention and the subject matter of claims 6-15, 17, 19 and 20 stands withdrawn under 37 CFR 1.142(b) as being for non-elected subject matter. The remaining products which are not within the elected invention, which are independent and distinct from the elected invention and do not have unity with the elected compound and are therefore withdrawn by means of a restriction requirement within the claims are,

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for example, the products of formula I wherein: L1 is -O-, -S-, -N-, -CO₂-, -OCO₂-, -SO-, -SO₂-, -CSN(R₈)-, -CON(R₈)O-, -CON(R₈)-, -OCON(R₈)-; R_{6a} and R_{6b} are -OR₉, -N(R₉)₂, CO₂R₉, -CON(R₉)₂, NHCOR₉, =NR₉, -R₉; R₉ is hydrogen, aryl or alkylenearyl; or two R₉ units can be taken together to form a substituted or unsubstituted carbocyclic or heterocyclic ring comprising from 3 to 7 atoms; m is 0 or 2-5; R₇ is nil, hydrogen, alkyl, heteroalkyl, hydrocarbyl, heterocycle, heteroaryl or alkyleneheteroaryl; R₇ and a R₉ can be taken together to form a substituted or unsubstituted carbocyclic or heterocyclic ring comprising from 3 to 7 atoms; j is 1 to 5; L₂ is -O-, -S-, N, CO₂, CO, OCO₂, SO, SO₂, CSN(R₁₀), CON(R₁₀)O, OCON(R₁₀); R_{11a} and R_{11b} are as found in claim 1; g is 1 to 5; R₁₂ is nil, heterocycle, aryl, alkylenearyl, heteroaryl or alkyleneheteroaryl; R₁₂ and R₁₃ can be taken together to form a substituted or unsubstituted carbocyclic or heterocyclic ring comprising from 3 to 7 atoms; n is 1 to 5; L₃ is O, S, N, CO₂, CO, OCO₂, SO, SO₂, CSNH, CONH, OCONH; R₁₆ is alkyl, heteroalkyl, aryl, alkylenearyl, heterocyclyl, heteroaryl or alkyleneheteroaryl; R_{4a}, R_{4b}, R_{4c} and R₅ are a substituted unit; or R₂ and R_{4a}, R_{4a} and R_{4b}, R₁ and R₂, or R₁ and R₃ can be taken together to form a carbocyclic or heterocyclic ring comprising from 3 to 7 atoms.

The above mentioned withdrawn products which are withdrawn from consideration as being for no elected subject matter differ materially in structure and composition from the compounds of the elected invention. The withdrawn compounds differ from those of the elected invention, such as, for example, by a thiazolidine, quinoline, thiophene, morpholine, oxazole, pyramiding, pyrazine, pyran, furan, etc.,

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which are chemically recognized to differ in structure, function, and reactivity. This recognized chemical diversity of the compounds can be seen by the various classification of these compounds in the U.S. classification system, i.e. class 549 subclass (200)+ furanyl, class 549 subclass (1)+ thiophene, class 548 subclass (215)+ oxazole and class 548 subclass (146)+ thiazole, etc. Therefore, again, the compounds which are withdrawn from consideration as being for non-elected subject matter differ materially in structure and composition and have been restricted properly as a reference which anticipated but the elected subject matter would not even render obvious the non-elected subject matter. These withdrawn compounds are independent and distinct from the elected invention and do not have unity with the species elected and are therefore withdrawn by means of a restriction requirement within the claims.

The requirement is still deemed proper.

Claim Objections

Claim 2 is objected to because of the following informalities: Claim 2 does not have the required period at the end of the sentence. Appropriate correction is required.

Claims 1-5, 16, 18 and 21 are objected to as containing non-elected subject matter. Claims 1-5, 16, 18 and 21 presented drawn solely to the elected invention identified supra as: the elected invention for search and examination, would overcome this objection.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 16 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Specifically, claim 16 recites the limitation “-CON(R8)-” in “L2”. There is insufficient antecedent basis for this limitation in the claim as L2 is not defined in parent claim 2 (and claim 1) to include the substituent -CON(R8). L2 is only defined in claim 1 as “selected from the group consisting of covalent bond, -O-, -S-, -N-, -CO2-, -CO-, -OCO2-, -SO-, -SO2-, -CSN(R10)-, -CON(R10)-, -CON(R10)O-, -OCON(R10)-...” Therefore, claim 16 is rejected as being indefinite as the limitation of -CON(R8) in L2 lacks antecedent basis which makes the scope of the claim indeterminate.

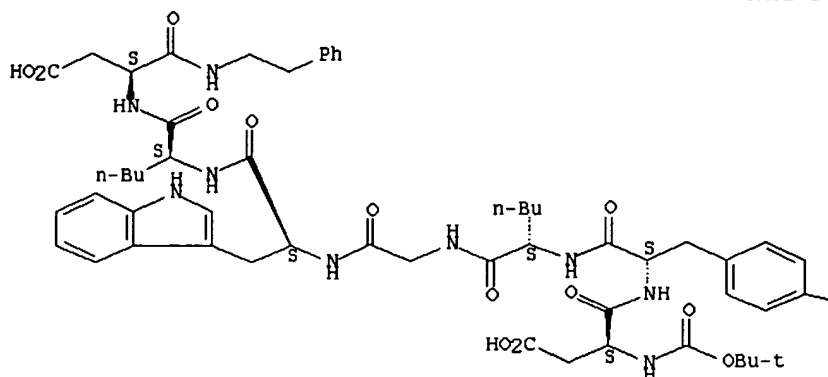
Non-elected Subject Matter Claim Rejections - 35 USC § 102

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

The non-elected subject matter of claims 1-5, 16 and 21 are rejected under 35 U.S.C. 102(b) as being anticipated by Galas et al.

Galas et al. discloses the compound of derivative No. 10, Table 1 page G178 and page G179, Table 2. Table 2 discloses the biological activities of the compounds. The compound of derivative No. 10 has the formula:

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which corresponds to applicants instantly claimed invention of compounds and pharmaceutical compositions, for example, wherein: R5 is H; R4c, R4b, and R4a are hydrogen; R2 is $-(CH_2)_j-L_2-[C(R_{11a}R_{11b})_gR_{12}]$ wherein j is 0, L2 is CON(R10), R10 is H, g is 0 and R12 is substituted or C1-C10alkyl or substituted hydrocarbyl; R3 is $-(CH_2)_n-L_3-R_{16}$ wherein n is 0, L3 is a bond and R16 is hydrogen; and R1 is $-L_1-[C(R_{6a}R_{6b})]_mR_7$ wherein L1 is $-CO-$, m is 1, one of R6a and R6b is hydrogen and the other is $-NHCO_2R_9$ wherein R9 is C1-C5 alkyl, and R7 is substituted C1-C10alkyl (or one of R6a is substituted C1-C5alkyl, the other is $-NHCO_2R_9$, and R7 is H).

Conclusion

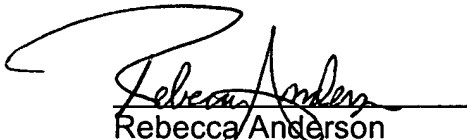
Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Rebecca L. Anderson whose telephone number is (571) 272-0696. Mrs. Anderson can normally be reached Monday through Friday 5:30AM to 2:00PM.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Mr. Joseph K. McKane, can be reached at (571) 272-0699.

The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



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December 21, 2005